DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 19, 2015

U&U Medical Technology Co., Ltd.
C/O Ms. Li Qian
Official Correspondent
CARELIFE (USA), Inc.
1580 Boggs Rd. Suite 500/600
Duluth, Georgia 30096

Re: K143629
Trade/Device Name: U&U Bowie-Dick Test Pack
Regulation Number: 21 CFR 880.2800
Regulation Name: Chemical Indicator/Physical/Chemical sterilization process indicator
Regulatory Class: II
Product Code: JOJ
Dated: April 15, 2015
Received: April 20, 2015

Dear Ms. Li Qian:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143629

Device Name
U&U Bowie-Dick Test Pack

Indications for Use *(Describe)*
U&U Bowie-Dick Test Pack are designed for testing air removal efficiency of dynamic-air-removal prevacuum steam sterilizers operating at 134 degree C (273 degree F) for 3.5 minutes. The U&U Bowie-Dick Test Pack is for single use and will demonstrate a uniform color change from yellow to dark brown/black when proper sterilization conditions are met and no air is present. If enough air is present to create a 2°C (+1°C /-0°C) temperature difference between the center of the Bowie-Dick Test Pack, as identified in ANSI/AAMI/ISO 11140-5, and the drain temperature at the beginning of the final one minute of a three and half minute cycle the U&U Bowie-Dick Test Pack will demonstrate a non-uniform color change

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Sec 005_510(K) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

Date Prepared: **2015-05-15**
Submission Numbers for Pre-Submission: **K143629**

1. Submitter Name and Address:

Name: U&U Medical Technology Co., Ltd
Address: Dongzhou Village,Hengshanqiao,Changzhou,Jiangsu,China
RM EE1092 1/F Building 1, No 1755, HONGMEI Road, Shanghai, China
Contactor Name: Garfield Wang
TEL: +86-13902471751
E-mail: Wangxuebo_11@hotmail.com

US Agent:
Name: CARELIFE (USA) INC.
Address: 1580 Boggs Rd, Suite 500/600 Duluth GA 30096
TEL: 404 6612228
Contact person : Ms. LI QIAN liqian@shanghaicarelife.com

2. Submission Devices Information:

Trade/Proprietary Name: U&U Bowie-Dick Test Pack
Common Name: Bowie-Dick Test Pack
Classification name: indicator, physical/chemical sterilization process
Class: II
FDA review panel code: General Hospital
Product code: JOJ
Regulation Number: 21 CFR 880.2800

3. Predicate Devices Information:

Trade Name: 3M Comply Bowie-Dick Type Lead Free Test Pack
510(K) Number: K093199
Manufacturer: 3M Health Care

4. Devices Description:

The U&U Bowie-Dick Test Pack is equivalent in performance to the Bowie-Dick towel pack described in AAMI ST66. The test pack consists of a chemical indicator test sheet positioned within a pack of porous sheets. The test sheet contains a steam-sensitive chemical indicator ink printed on paper as a yellow-colored pattern. The test sheet will turn a uniform dark brown/black color except when air removal failures such as air leaks occur. An air removal failure is indicated by a lighter-colored area in the indicator ink pattern of an otherwise dark-colored test sheet.

Model Number：

Ref Number	Model Number	Description	Size
UUBD0001	UUBDTP	U&U Bowie-Dick Test Pack	140X140X18mm

5. Intended Use:

U&U Bowie-Dick Test Pack are designed for testing air removal efficiency of dynamic-air-removal prevacuum steam sterilizers operating at 134 degree C (273 degree F) for 3.5 minutes. The U&U Bowie-Dick Test Pack is for single use and will demonstrate a uniform color change from yellow to dark brown/black when proper sterilization conditions are met and no air is present. If enough air is present to create a 2°C (+1°C /-0°C) temperature difference between the center of the Bowie-Dick Test Pack, as identified in ANSI/AAMI/ISO 11140-5, and the drain temperature at the beginning of the final one minute of a three and half minute cycle the U&U Bowie-Dick Test Pack will demonstrate a non-uniform color change

6. Technical Design and Performance Characteristics:

The U&U Bowie-Dick Test Pack uses impermeable layers on the top and bottom to direct steam and enhances the air capture qualities. A precisely controlled pad of porous substrate is used to establish a matrix for the formation of an air bubble and to act as a reservoir of air simulating the towels in a conventional large towel pack.

The reticulated foam layer acts as a steam pathway for the control of air bubble alignment and insulates the indicator from radiant heat emanating from the hot surface of the sterilizer chamber. Air is evacuated from the chamber and the test pack during the pre-vacuum cycle. If an air leak is present, air will bleed back into the chamber as a vacuum is pulled. Since air is much cooler and heavier than steam, it will be forced to the bottom of the chamber near the drain when the steam valves opens. As pressure begins to increase, the air and then the steam enters the pack from the sides and top of the reticulated foam pathway at the top of the pack. The steam pressure compresses the air into a bubble and pushes it toward the bottom of the pack. As the steam pressure increases, the air bubble is squeezed smaller and smaller until the pressure stabilizes.

7. SUBSTANTIAL EQUIVALENCE DISCUSSION:

U&U Medical Technology Co., Ltd is claiming substantial equivalence for its U&U Bowie-Dick Test Pack to the 3M Comply Bowie-Dick Type Lead Free Test Pack (K093199) based on test data obtained during validation studies. We have demonstrated with testing that the U&U Bowie-Dick Test Pack performs consistently with results which indicate that the indicator is sensitive enough to detect when enough air is left within the sterilizer chamber to create a 2°C (+1° /-0°C) temperature difference between the center of the Bowie-Dick Test Pack, as identified in ANSI/AAMI/ISO 11140-5. Under these conditions, the indicator sheet would demonstrate a non-uniform color change. The U&U Bowie-Dick Test Pack is also comparable to other commercially available Bowie Dick test packs cleared by the FDA.

Comparison table:

Element of Comparison	Submission Device	Predicate Device K093199
Intended Use	U&U Bowie-Dick Test Pack are designed for testing air removal efficiency of	The 3M™ Comply Tm Bowie-Dick Type Lead Free Test Pack is designed for testing air

	dynamic-air-removal prevacuum steam sterilizers operating at 134℃ (273℉) for 3.5 minutes. The U&U Bowie-Dick Test Pack is for single use and will demonstrate a uniform color change from yellow to dark brown/black when proper sterilization conditions are met and no air is present. If enough air is present to create a 2°C (+1° /-0°C) temperature difference between the center of the Bowie-Dick Test Pack, as identified in ANSI/AAMI/ISO 11140-5, and the drain temperature at the beginning of the final one minute of a three and half minute cycle the U&U Bowie-Dick Test Pack will demonstrate a non-uniform color change	removal efficiency of 132- 134℃(270- 273℉) dynamic-air-removal steam sterilizers.
Raw Materials	Impermeable Layer - Frame Board Reticulated Foam - Polyurethane Porous Substrate - Food Packaging Board Indicator Sheet - Indicator ink & paper Disposable Wrap - Polypropylene Wrap Label - Paper & Hotmelt Adhesive	Impermeable Layer - Frame Board Reticulated Foam - Polyurethane Porous Substrate - Food Packaging Board Indicator Sheet - Inicator ink & paper Disposable Wrap - Polypropylene Wrap Label - Paper & Hotmelt Adhesive
Indicator Agent	Indicator Ink - Lithium carbonate (5-10%), Triethylamine(1-5%) , Normal Propanol(1-5%)	Indicator Ink - unknown
Chemical Indicator Type	Air Removal Indicator For Test Pack	Air Removal Indicator For Test Pack
Endpoint Color	Dark brown/Black	Dark brown/Black
Sterilization Method	dynamic-air-removal steam sterilizer	dynamic-air-removal steam sterilizer
Indictor Color Change Performance	The bowie-dick internal indicator system shall show a uniform color after exposure to saturated steam at 134°C for 3.5 min.	The bowie-dick internal indicator system shall show a uniform color after exposure to saturated steam at 134°C for 3.5 min.
Internal Indicator Color Change Fault Performance	Color change fault condition (the temperature at the center of the bowie-dick test pack is 2°C lower than the temperature of the chamber drain at the beginning of the final 1 min of a 3.5 min cycle at 134 °C). After exposure to conditions used to produce a color change fault condition in the bowie-dick test pack. the internal indicator shall show a non-uniform color change.	Color change fault condition (the temperature at the center of the bowie-dick test pack is 2°C lower than the temperature of the chamber drain at the beginning of the final 1 min of a 3.5 min cycle at 134 °C). After exposure to conditions used to produce a color change fault condition in the bowie-dick test pack. the internal indicator shall show a non-uniform color change.
Recommended Storage Conditions:	Store in a dry (<50% RH) condition at room temperature [15-30°C (59-86°F)] and protect from direct light. Do not store near strong alkaline or acidic products such as cleaning or disinfecting agents. After use the indicator will not change visually within 24 months when stored at above conditions.	Store in a dry (<50% RH) condition at room temperature [15-30°C (59-86°F)] and protect from direct light. Do not store near strong alkaline or acidic products such as cleaning or disinfecting agents. After use the indicator will not change visually within 24 months when stored at above conditions.
Shelf Life	The U&U BOWIE-DICK Test Pack has a 2-year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the label that secures the test pack.	The 3M™ Comply™ Bowie-Dick Type Lead Free Test Pack has a 2-year shelf life from the date of manufacture when stored at recommended conditions. The expiration date is printed on the label that secures the test pack.

Package Material	Paper Box	Paper Box

8. Recommended Storage Conditions:

Store in a dry (<50% RH) condition at room temperature [15-30°C (59-86°F)] and protect from direct light. Do not store near strong alkaline or acidic products such as cleaning or disinfecting agents. After use the indicator will not change visually within 24 months when stored at above conditions.

9. Non-Clinical Testing:

Validation of the U&U Bowie-Dick Test Pack included performance testing in dynamic-air-removal steam sterilizer, biocompatibility, storage condition, shelf life. All results, from testing meet the predetermined acceptance criteria.
All testing followed the FDA Guidance document for Industry and FDA Staff entitled, "Premarket Notification [5 10(k)] Submissions for Chemical Indicators,". And AAMI ST66: Sterilization of healthcare products - Chemical indicators - Part 2: Class 2 indicators for air removal test. And AAMI/ANSI/ISO 11140-5 Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick-type air removal test sheets and packs

Testing Items	**Code Requirement**	**Test Result**
Visual inspection	Inspect the Cleanliness of Bowie-dick test pack.	PASS
Dimensions	Width: 140±1mm Length: 140±1mm Height: 18±1mm	PASS
Endpoint Color	Dark brown/black	Black
Indicator Format	The bowie-dick internal indicator ink shall be uniformly distributed on its substrate paper to cover not less than 30 % of the test area of the substrate paper. the indicator ink printed / the substrate paper ⩾ 30%	66%
Indictor Color Change Performance	The bowie-dick internal indicator system shall show a uniform color after exposure to saturated steam at 134°C for 3.5 min.	PASS
Internal Indicator Color Change Fault Performance	Color change fault condition (the temperature at the center of the bowie-dick test pack is 2°C lower than the temperature of the chamber drain at the beginning of the final 1 min of a 3.5 min cycle at 134 °C). After exposure to conditions used to produce a color change fault condition in the bowie-dick test pack. the internal indicator shall show a non-uniform color change.	PASS
Air Permeance Performance	The bowie-dick test pack shall have an air porosity not less than 1.7 μm/(Pa·s) when tested in accordance with ISO 5636-3 at an air pressure of 1.47 kPa	PASS
Toxicity	Non-toxic; In Vitro Cytotoxicity (MTT cytotoxicity test) Test Result: Under the conditions of cytotoxicity study, the viability of 100% extract of	PASS

	the test article was 76 %. It can be considered that the article extracts had not a cytotoxic potential.	

10. Conclusion:

U&U Medical Technology Co., Ltd is claiming substantial equivalence for its U&U Bowie-Dick Test Pack to the 3M Comply Bowie-Dick Type Lead Free Test Pack (K093199) based on test data obtained during validation studies. We have demonstrated with testing that the U&U Bowie-Dick Test Pack performs consistently with results which indicate that the indicator is sensitive enough to detect when enough air is left within the sterilizer chamber to create a 2°C (+1° /-0°C) temperature difference between the center of the Bowie-Dick Test Pack, as identified in ANSI/AAMI/ISO 11140-5. Under these conditions, the indicator sheet would demonstrate a non-uniform color change.

11. BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

Based on the intended use, technological characteristics, performance data and nonclinical tests performed, the subject U&U Bowie-Dick Test Pack is substantially equivalent and is as safe and as effective as the legally marketed predicate device, 3M Comply Bowie-Dick Type Lead Free Test Pack cleared under K093199'.

END